## THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 18

## UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_\_

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

\_\_\_\_

Ex parte PETER B. SAMUELSEN, DORTE U. NIELSEN

Appeal No. 1997-0496 Application No. 08/387,935

HEARD: February 10, 2000

Before OWENS, LIEBERMAN, and KRATZ, <u>Administrative Patent Judges</u>. LIEBERMAN, <u>Administrative Patent Judge</u>.

#### **DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 from the examiner's refusal to allow claims 1 through 21 which are all the claims in the application.

#### THE INVENTION

The invention is directed to a dressing for dosing medicaments. There is at least one medicament containing layer. A barrier layer is situated between the medicament layer and a release face. The barrier layer contains a continuous hydrophobic phase and

dispersed therein a discontinuous hydrophilic phase. The hydrophilic phase is either water soluble or water swellable.

## THE CLAIMS

Claim 1 is illustrative of appellants' invention and is reproduced below.

1. A dressing for dosing one or more medicaments and comprising at least one medicament containing layer and a barrier layer arranged between the medicament containing layer and a release face,

characterized in that the barrier layer is a continuous hydrophobic phase and a discontinuous hydrophilic phase which is dispersed therein and which is water soluble or water swellable.

#### THE REFERENCES OF RECORD

As evidence of obviousness, the examiner relies upon the following reference.

Horstmann et al. (Horstmann)

5,230,898

Jul. 27, 1993

#### THE REJECTIONS

Claims 1 through 21 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as unpatentable over Horstmann.

#### OPINION

We have carefully considered all of the arguments advanced by appellants and the examiner and agree with appellants that the aforementioned rejections under 35 U.S.C. §§ 102(b) and 103 are not well founded. Accordingly, we do not sustain the examiner's rejections.

Appeal No. 1997-0496 Application No. 08/387,935 Page 3

## The Rejection under §§ 102(b) and 103

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." See In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The examiner relies upon a reference to Horstmann to reject the claimed subject matter and establish a *prima facie* case of unpatentability. The basic premise of the rejection is that the primary reference to Horstmann discloses a multilayer transdermal therapeutic system, wherein the medicament layer is essentially the same as the claimed barrier layer. See Answer, page 5. In addition, Horstmann teaches, a barrier layer, an adhesive layer and contemplates alternative arrangement of layers. See Answer page 6 and 7.

We find that the multilayer transdermal therapeutic system of Horstmann is taught in Figure 1. The first layer is a backing layer (11). Adjacent to the backing layer is a layer with a matrix having an active substance present, such as a medicament of the claimed subject matter (12). Adjacent to the active substance containing layer is a barrier layer, which controls the access of liquids (13). Atop the barrier layer is a removable protective layer (16). The matrix containing layer includes, in addition to the medicament, a hydrophobic phase including polyisobutylene, polymers of styrene and unsaturated hydrocarbon resins and water swellable hydrophilic materials, which includes cellulose and its derivatives. See column 3, line 67 through column 4, line 16 and Example 1.

While we accept the examiner's premise that the layer of Horstmann having the matrix and active substance, i.e. medicament, is the same as appellants' barrier layer, the premise fails to provide for an additional medicament containing layer as required by the claimed subject matter. Hence it neither anticipates nor renders obvious the claimed subject matter.

Furthermore, we determine that the barrier layer of Horstmann which controls the access of liquid to the medicament layer contains neither a water soluble nor water swellable hydrophilic phase as the discontinuous phase in a hydrophobic matrix.

Based upon the above analysis, we have determined that the examiner's legal conclusion of anticipation and obviousness is not supported by the facts. Accordingly, we do not sustain the examiner's rejections.

# **DECISION**

The rejection of claims 1 through 21 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as unpatentable over Horstmann is reversed.

The decision of the examiner is reversed.

# REVERSED

TERRY J. OWENS Administrative Patent Judge	) ) )
PAUL LIEBERMAN Administrative Patent Judge	) ) BOARD OF PATENT ) APPEALS ) AND ) INTERFERENCES )
PETER F. KRATZ Administrative Patent Judge	) ) )

PL/jlb

Appeal No. 1997-0496 Application No. 08/387,935

Page 7

OSTROLENK FABER GERB AND SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 10036-8403